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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/447,490 11/23/99 ECKARDT

R 0691-018A/GP

EXAMINER

MCKENZIE, T

ART UNIT

PAPER NUMBER

1611

DATE MAILED:

01/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/447,490	Applicant(s) ECKARDT ET AL.	
	Examiner Thomas C. McKenzie, Ph. D.	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

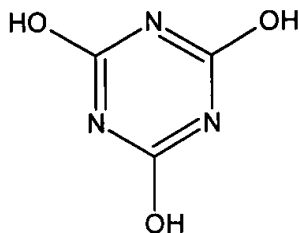
- | | |
|---|--|
| 14) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 16) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 19) <input type="checkbox"/> Other: _____ |

Art Unit: 1611

DETAILED ACTION

1. This is a response to application and preliminary amendment filed 11/23/99. There are seven claims pending, claims 2-8, directed to a process of making carbamazepine. Examiner is using PTO 95-4841 translation of Acklin (EP 277,095). The US equivalent of this patent is 4,847,374. Examiner also has the board decision (1996-1528) from the parent application. Examiner has noted a typo in the use of "cyanuric acid" when "cyanic acid" is intended in both the translation and in the board decision. Examples are found on page 4 of both documents, in lines 16 and 18 of the decision and lines 6 and 22 of the translation. There has been confusion between "cyanide" and "cyanate" also.

HOCN = HNCO = cyanic acid = isocyanic acid = Cyansaure
NaNCO = sodium cyanate = sodium isocyanate = Natriumcyanat
NaCN = sodium cyanide = Natriumcyanid
HCN = hydrogen cyanide = hydrocyanic acid = Cyanwasserstoff



cyanuric acid = Cyanursäure

Art Unit: 1611

Cyanic acid and isocyanic acid are tautomers, differing only as to the placement of the hydrogen atom, and are in rapid equilibrium. Cyanides and hydrogen cyanide are not capable of converting iminostilbene to carbamazepine because their carbon atom is in the wrong oxidation state.

Specification

2. The disclosure is objected to because of the following informalities: page 2 line 15 and page 3 line 3, "hydrogen cyanide" is used when cyanic acid is meant. Repeatedly in the working examples, as on page 6 lines 8 and 13, the phrase "sucked off" is used. Examiner suggests "collected by filtration". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The aqueous

Art Unit: 1611

alcohol choice, as part of the acidic medium, is not itself described in the specification or any of the working examples. There is no mention of the use of aqueous alcohol as a concept although the individual components are mentioned.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim would read the same if the word "optionally" were not present. Since we do not know what applicants intend by this word, the claim is indefinite.

Claim Rejections - 35 USC § 102 and 103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

Art Unit: 1611

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The current claim 8 differs from claim 1 in 08/275,025 by inserting the phrase "an acidic medium consisting of" before acetic acid, adding "optionally", replacing within by "with", and adding the phrase "or with an aqueous alcohol". The net result is that there are now four rather than three possible solvents. These solvents are acetic acid, aqueous acetic acid, a mixture of acetic acid and alcohol, or a mixture of all three. Acetic acid is an acid so by definition it is an acidic medium. The claim is thus slightly broader than the claim rejected by the board.

7. Claims 2-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious by Acklin (EP 277,095) with evidence supplemented by Patterson's "German-English Dictionary for Chemists".

8. The Acklin reference was discussed in the Board of Patent Appeals and Interferences decision. In addition, claim 14 of Acklin reads in the German "dass man als saures Mittel und gleichzeitig als Losungsmittel Essigsäure verwendet." Line 54-56 of page 16 of the English translation reads "that the acidic acid and the solvent are acetic acid". This does not make grammatical nor chemical sense and the "acidic acid" phrase appears redundant. This is the result of a typo regarding

Art Unit: 1611

“saures Mittel” in the English translation. The phrase “saures Mittel” is “acidic agent” not acidic acid”. A more accurate translation of claim 14 of Acklin is “one uses acetic acid as acidic agent and solvent simultaneously.” Note that “agent” replaces “acid” and “simultaneously” has been added. In column 2 line 63 and column 3 line 4 of the German patent, the same phrase “sauren Mittels” appears. In line 23 “saure katalytische Mittel” and in line 27 “saures Mittel” appear in the German original. In these cases but not in claim 14, “Mittel” has been correctly translated “agent”. This is on page 6 of the English translation in lines 6, 10, 25, and on page 7 line 3. Further in support of this reading is the definition of “Mittel” in Patterson’s “German-English Dictionary for Chemists” which renders it as “agent or means”. Patterson’s rendering of “gleichzeitig” is “simultaneously”. Thus, no other acid is required by claim 14 of Acklin. Acklin teaches not only using acetic acid as the catalyst and as solvent, as set forth by the Board of Patent Appeals and Interferences, but also teaches acetic acid as the sole acidic agent. Claim 14 of Acklin teaches that the disclosed process is not limited to the preferred acidic agents i.e. formic acid or stronger. Hence, all elements of applicants’ process are present, including use of acetic acid as the acidic agent.

Art Unit: 1611

9. Regarding claims 2-4, on page 4 line 25 of the translation, Acklin teaches carrying out the reaction in "mostly water- alcohol- and amine-free" conditions. Since we do not know what mostly means it is clear a few percent of these substances may be present in a suitable solvent. Claims 2-4 includes the range zero to a few percent water or alcohol.

10. Regarding claim 5, Acklin teaches using alkali cyanates. Example 2 of Acklin teaches a process comprising adding NaNCO to iminostilbene in acetic acid.

11. Regarding claim 7, on page 4 line 10 of the translation Acklin teaches that preferred salts are the sodium and potassium.

12. Alternatively, applicants' process is obvious for reasons set forth by the Board of Patent Appeals and Interferences. All the elements are present in Acklin. The new "acidic medium" language not present in the 08/275,025 application does not distance applicants claims from the reference as Acklin used an acidic medium.

13. Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acklin. Claim 14 is not the only teaching of Acklin bearing on the current application. The second and third paragraphs of page 4 of the English translation describe production of the required HNCO by treatment of an alkali cyanate with

Art Unit: 1611

an acid and that acetic acid is a suitable solvent for the reaction with iminostilbene. Working examples 9 and 10 spanning pages 13 and 14 of the translation teach reaction of iminostilbene with HNCO in acetic acid with no additional acids present. This would render obvious preparing the HNCO *in situ*. Claims 5 and 6 of Acklin teach releasing and using HNCO from alkali cyanates without isolating the HNCO. Dependant claim 7 of Acklin teaches doing the release of HNCO in acetic acid. Regarding claim 5, changing the order of addition is an obvious variation to one of ordinary skill in synthetic organic chemistry.

Allowable Subject Matter

14. Claim 6 is rejected as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim. Acklin does not teach adding water to the reaction mixture.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. McKenzie, Ph. D. whose telephone number is (703) 308-9806. The examiner can normally be reached on 8:30 to 5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on (703) 308-4716. The fax phone

Art Unit: 1611

number for the organization where this application or proceeding is assigned is (703) 308-4556 for regular communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

TCMcK *TCM*
January 20, 2000



SEARCH
PRIMARY EXAMINER
GROUP 120 - ART UNIT 1